MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations 2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.

2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.

3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.

4. The authorisation is not transferable to another legal entity.

5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:

   - there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product
   - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
   - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012 (SI 2012/1916).

6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance with, The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]

7. If the intention is to import licensed medicinal products from outside the EEA an application for a manufacturer's licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.

8. If the intention is to import a special medicinal product from outside the EEA into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.

9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.

10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.

11. The Medicines and Healthcare Products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).

12. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.

13. Authorisation Structure

    This Wholesale Distribution Authorisation is divided into five annexes.

    (a) Annex 1: Scope of wholesale distribution authorisation
    (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
    (c) Annex 3: Name(s) of responsible person(s.)
    (d) Annex 4: (Optional) Date of Inspection on which authorisation was granted
    (e) Annex 5: Additional provisions based on national requirements

Attention is drawn to the structure of this authorisation and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.

14. Authorisation Holder

(a) Authorisation Holder Number: WDA(H) 13985 has been granted to –

AUTHORISATION HOLDER:	BARCLAY PHARMACEUTICALS LIMITED

TRADING AS:	ENTERPRISE/TRIDENT/VANTAGE/AAH/Careway
ADDRESS:	WEST AVENUE, TALKE, STOKE ON TRENT, ST7 1TL, UNITED KINGDOM
CONTACT NAME:	Mr G Williams

(b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.

(c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.

(d) Date granted - 27/04/2017

(e) Authorised by -

Name: Yaseen Edoo

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 27/04/2017

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VARIATION HISTORY

Date	Variation Detail
14/07/1994	INITIAL APPLICATION
18/10/1994	VARIATION
25/04/1995	To delete Mr G Winkle & Insert Mr MD Yorke as RP.I have checked details for new RP and I am happy that the requirements have been please confirm if you have any objections.Also site 7881 has now been deleted as per letter dated 31/3/95
19/07/1995	To delete site
24/11/1995	Change of Licence holder address and communication address.
04/02/1997	Renewal with R.P changes for the Atherstone Site, Enterprise Site and the Trident Pharmaceuticals Site. 31/7/96: Added T/A name to Atherstone site
02/06/1997	Multiple admin variation.-(1)-Delete sites at Belfast(8054),York(1040),Cambridge(8349),Glasgow(1033) and Derby(3260).-(2)-Delete RP Mr Yorke(5576)from sites 256(Avonmouth),1229(Carlisle),2110(Coulsdon),3261 (Grassmoor) and 3262(Ashton).-(3)-Delete RP Mr Jack 5576 from Atherstone site(1788).-(4)-Add Mr Wood (5765) as RP to sites 256, 1229, 1788, 2110, 3261 and 3262.-(5)-Change L/H address from Derby to AAH headquarters in Morley, Leeds.
13/06/1997	Administrative var. to delete following sites 0256 Avonmouth 1229 Carlisle 2110 Coulsdon 3261 Grassmore 3262 Ashton-under Lyne.
05/10/1998	Deletion of Atherstone site (1788): this site henceforth appears on WL/11545 (A.A.H. Pharmaceuticals).
23/10/2000	Variation to change L/H and Communication addresses and L/H Contact.
01/03/2002	Renewal with changes to change licence holder contact, add Wx, Wi and SI to site 8441 and Wx and SI to site 3090
20/03/2002	Variation to add additional site 10142.
01/08/2002	Variation to add Cardway (11578) site.
06/08/2002	Variation to delete AstraZeneca Newcastle Distribution site.
14/04/2003	Variation to add Mr David Gittins and Peter Blundell as RP person.
25/11/2003	Variation to revise site names to include a trading style and delete site 8441.

08/11/2006	Variation to remove sites 21421, 2398 and replace with new site 296046.
06/06/2007	Variation to Change company name back to Barclay Pharmaceutical Ltd and add AAH site as a new site.
16/01/2008	Variation to replace Mr P Blundell with Mr G Williams as Responsible Person on the STOKE site.
15/05/2008	Variation to add AAH Pharmaceuticals Limited, Castlereagh, Belfast as an additional site.
08/09/2008	Variation to delete Mr D T Gittins as the licence holder and also as an RP for site 296046. Add Mr G Williams as the new licence holder contact.
15/11/2010	Variation to (1) Replace Mr J C Wood and Mr P A Barratt with Mr G Willams as RP for Sites 4013 & 90083 (2) Change the communications contact to Miss Hayley Rolph
23/08/2012	Variation to delete site 90083 and change communication contact to Mrs C Makepeace, add Miss N Evans as an RP to the licence.
01/10/2012	Variation to add cold chain products to both sites.
08/07/2013	Variation to add site 4040
08/08/2013	Variation to amend functions of site 296046
14/10/2013	FMD update WL/WDL converted to WDA(H)
27/10/2014	Variation: Remove 1.2, 3.3, 3.1.2, 3.1.3 and add Homeopathic medicinal products to categories of products handled at the site.
22/04/2015	Variation: 1. Add T/A Careway. 2. Add cold chain and add 3.1.2 & 3.1.3.
23/09/2016	Variation: Add new administrative site 5869.
27/04/2017	Variation: Add new trading style ENTERPRISE/TRIDENT/VANTAGE/AAH/Careway

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Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	BARCLAY PHARMACEUTICALS LIMITED
Address:	WEST AVENUE, TALKE, STOKE ON TRENT, ST7 1TL, UNITED KINGDOM
MHRA Site Number:	296046

is named on Authorisation Holder number: WDA(H) 13985 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations

Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

1.1 With a Marketing Authorisation in EEA member state(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	BARCLAY PHARMACEUTICALS LIMITED
Address:	WEST AVENUE, TALKE, STOKE ON TRENT, ST7 1TL, UNITED KINGDOM
MHRA Site Number:	296046

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

4.5 Traditional Herbal Medicinal products

4.6 Homeopathics

MHRA
Regulating Medicines and Medical Devices

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Annex 2 – Address(es) of Contract Wholesale Distribution Sites and their Authorisation Number

Site Name	Address	Authorisation Holder Number	MHRA Site Number
AAH PHARMACEUTICALS LIMITED	SAPPHIRE COURT, WALSGRAVE BUSINESS PARK, WALSGRAVE TRIANGLE, COVENTRY, CV2 2TX, UNITED KINGDOM	WDA(H) 11545	5869
AAH PHARMACEUTICALS LIMITED	CAVALRY HILL INDUSTRIAL PARK, WEEDON, NN7 4PP, UNITED KINGDOM	WDA(H) 11545	4013
AAH PHARMACEUTICALS LIMITED	CENTURION HOUSE, CENTURION PARK, WATLING STREET, WILNECOTE, TAMWORTH, B77 5PZ, UNITED KINGDOM	WDA(H) 11545	4040

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Annex 3 – Name(s) of designated Responsible Person(s)

Personnel

Responsible Person			
Person Number	**Name**	**Site**	**Role**
1322735	Miss N Evans	296046	Responsible Person
1298344	Mr G Williams	296046	Responsible Person